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| 10/698,795 | 10/31/2003 | Sabina Cauci | 13581 US | 1736 |

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EXAMINER

GITOMER, RALPH J

| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/698,795 | Applicant(s) CAUCI, SABINA | |
| | Examiner Ralph Gitomer | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group I in the reply filed on 2/6/06 is acknowledged. The traversal is on the ground(s) that there is a common technical feature. This is not found persuasive because the claims are properly defined as distinct where one Group is directed to a method and the other Group is directed to a kit. Further, this application was not filed under 371 and so such an argument does not apply to restriction practice.

The requirement is still deemed proper and is therefore made FINAL.

No claim for priority is made, therefor priority is granted to the date of this application on October 31, 2003. It is noted that sialidase is also known as neuraminidase. Upon resolution of the following issues under 35 USC 112, further searching and/or consideration may be required.

A reading of the specification reveals no specific point of novelty. Regarding the presently claimed cutoff values regarding odds ratios, no patentability is seen in claiming some particular point on a curve. No results are claimed for such cutoff values.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-8 of copending Application No. 10/470,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '690 also include antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-54 of copending Application No. 10/467,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because the three elements presently claimed together are claimed separately in different combinations in '357. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Soothill, Johnson, Lawrence, Cauci, Cauci, McGregor, and Briselden.

Soothill (WO 00/55354) entitled "A Diagnostic Test" teaches on page 4 a test for sialidase activity as an indicator of BV and therefor a predictor of the likelihood of preterm birth.

Johnson (WO 00/24753) entitled "Chromogenic Substrates of Sialidase and Methods of Making and Using the Same" teaches on page 2 first paragraph, measurement of sialidase level in vaginal samples could be used to diagnose bacterial vaginosis.

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Lawrence (5,571,684) entitled "Assay for Proline Iminoamidase and Other Hydrolytic Activities" teaches in column 2 first full paragraph, vaginal pH of women with BV or trich is above 4.5, whereas the normal vaginal pH is less than 4.5. In column 7 second full paragraph, the substrate detects peptidases where the substrate residue is proline. In column 12, line 61, vaginal fluid is tested.

Cauci (Am J Obstet Gynecol) entitled "Immunoglobulin A Response Against Gardnerella vaginalis Hemolysin and Sialidase Activity in BV" teaches in the abstract, there is a correlation between sialidase activity in vaginal fluids and bacterial vaginosis.

Cauci (J of Infect Diseases) entitled "Impairment of the Mucosal Immune System" teaches on page 1698, BV is associated with preterm delivery, chorioamnionitis, amniotic fluid infections, postcesarean endometritis, salpingitis, and HIV infection. On page 1701 sialidase activity correlated with BV and to a lesser extent prolidase where no prolidase activity was detected in healthy women.

McGregor (Am J Obstet Gynecol) entitled "Bacterial Vaginosis is Associated With Prematurity and Vaginal Fluid Mucinase and Sialidase" teaches in the abstract preterm birth and other adverse pregnancy outcomes are linked with infection. Sialidases from BV are associated with vaginal microorganisms and intrauterine infection and preterm birth.

Briselden (J of Clinical Micro) entitled "Sialidases (Neuraminidases) in BV and BV Associated Microflora" teaches in the abstract, BV is associated with prematurity and upper genital tract infection. Elevated levels of sialidase activity is highly associated with BV.

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The claims may differ from the above references in that they recite specific levels of sialidase and/or prolidase indicate some odds ratio value or score. Some dependent claims include a pH range determination and/or score.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to select a particular population of women at risk for pathologies by determining sialidase and/or prolidase because each of the above references teaches the same method for determining the risk of the same pathologies as claimed.

Regarding the selection of some odds ratio being calculated from some level of detected sialidase and/or prolidase, no novelty is seen in such selection because each of the references show data, usually presented as a curve, where at some cutoff some degree of correlation between enzyme levels detected and pathology may be inferred.

This is standard practice in clinical diagnosis. Regarding determining pH level of vaginal fluid as claimed, it is known and taught by some of the above references such as Lawrence that normal vaginal pH is below 4.5 and ranges above 4.5 are associated with BV and other pathologies.

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Claims 1-3, 5-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaginal fluid, does not reasonably provide enablement for "body fluid". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim the terms "body fluid" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such fluid would work in the instant invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to risk of developing obstetric or gynecologic pathologies in general. Claim 5 lists a number of pathologies including various sites of infection, STD's in general, and malignancies. It is not seen how the present invention could predict the risk of all such maladies. For example, does the invention predict the risk of a Nabothian cyst or ovarian carcinoma?

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative fluids claimed.
2. Amount of direction or guidance presented is insufficient to predict which fluids encompassed by the claims would work.
3. Presence of working examples are only for a single specific fluid and extension to other fluids has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related fluids are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of fluids.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be carefully rewritten in accordance with standard US patent practice.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chrispe (6,372,209) teaches a vaginal medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
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GROUP 1200